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May 22, 1999

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Dockets Management Branch  
The Food and Drug Administration  
Department of Health and Human Services, Rm. 1-23  
12420 Parklawn Dr.  
Rockville, MD 20857

Re: 99P-1340/CP 1  
Petition to Have "Eternity eau de parfum" Misbranded

Dear Sir or Madam:

In May, 1999, the Environmental Health Network (EHN) submitted the above petition to have Calvin Klein's "Eternity eau de parfum" declared misbranded. I am writing to give my full support to this petition and request that the FDA give it careful attention. FDA regulations 21CFR Sec. 740.1, 21CFR Sec. 740.2, and 21CFR Sec. 740.10. Regulation 21CFR Sec. 740.10 state:

"Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel: "Warning--The safety of this product has not been determined."

As the petition and data submitted therewith shows, "Eternity" contains toxic ingredients and ingredients, of which the safety has not been substantiated. And it contains no warning label on its packaging.

Calvin Klein claims their products "are manufactured with extreme care, under strict quality control procedures" and that "all ingredients and finished products are carefully evaluated before use." They further claim that while "it has been well documented that there are people [like me] who respond to scented items with like reactions" that reactions such as mine are "occasional." See enclosed letters to and from Calvin Klein dated May 30, 1990 and July 12, 1990, respectively. The data included with this petition shows these claims to be false.

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As consumers of products designed to be inhaled and absorbed into the body through the skin, we all have a right to know the status of safety testing of the ingredients in products such as "Eternity" so that we can protect ourselves and our families from toxic chemicals that may cause health problems. Most people are not aware that most fragrance materials have only limited safety testing. They wrongfully assume these products are safe to use in any setting and are surprised when people complain.

Like tobacco smoke, the harmful chemicals currently used in these products may effect the health of many people, including: people with asthma, chemical sensitivities, chronic fatigue, and other environmental illnesses. Small children are particularly vulnerable to toxic chemicals found in products purchased and used by their parents, care givers and teachers.

When I am exposed to fragrance products, such as "Eternity," I experience asthma symptoms and severe coughing attacks that leave me too weak to function; a lack of ability to concentrate; burning in the eyes, nose and chest; facial nerve and TMJ problems; migraines; and at times tremors and loss of motor control. These symptoms are not uncommon. You have only to look on Internet sites such as the following to read testimonials of others who suffer similar symptoms from exposures to fragrances.

Just last week, a woman at work (who is not allergic to perfumes) told me that someone gave her Eternity as a gift. She sprayed on "one spritz"; she and her coworker were so overcome by the fumes that she went to the bathroom and washed it off.

<http://members.aol.com/enviroknow/wall/index.html>  
[http://www.users.globalnet.co.uk/~aaair/perfume\\_corr.htm](http://www.users.globalnet.co.uk/~aaair/perfume_corr.htm)

Please act on behalf of the millions of people who have suffered physical illness and injury resulting from fragrance exposure at work, at school and in social settings. These toxic chemicals act as powerful barriers to the workplace, public buildings, hospitals and doctor offices, grocery stores, etc. by people disabled by asthma and chemical sensitivities. Because of this, toxic chemicals in fragrances have already ruined countless lives and will ruin those who unwittingly use or suffer symptoms from second-hand exposure to those toxic substances.

Sincerely,



Betty J. Krueger

Enclosures

bc: Barbara Boxer (email)  
Senator Diane Feinstein (email)

# Calvin Klein

July 12, 1990

Ms. Betty J. Kreeger  
1137 Shelter Creek Lane  
San Bruno, California 94066

Dear Ms. Kreeger:

We want to thank you for taking the time to contact us regarding an unfortunate experience you feel is related to your exposure to our ETERNITY fragrance. Calvin Klein Cosmetics Corporation realizes you are an important part of our Quality Assurance Program and appreciates your concern.

ETERNITY, as well as all of our products, undergoes a series of developmental processes before a product is approved. Our Marketing Department then evaluates many variables, including how you, the consumer, will react to our products. This particular product has been used by thousands and has received a very favorable response.

We wish to assure you that all of our products are manufactured with extreme care, under strict quality control procedures. Furthermore, our products have an excellent safety profile. We use high quality ingredients which have a long history of acceptability for use in bath and cosmetic products. All ingredients and finished products are carefully evaluated before use. However, occasionally an individual can experience an unpredictable allergic reaction to something which is in use every day by thousands of others. Examples are persons who suddenly display allergic reactions to common everyday foods (such as milk products, tomatoes, strawberries) or common medications (such as penicillin).

It has been documented that there are people, such as yourself, who respond to scented items with like reactions. However, research to date has not identified any specific ingredients.

So that we can try to help with your problem, we would like your assistance with the following items:

1. If you will take a few moments to fill out and return the enclosed questionnaire, it will help us to fully understand your experience and determine a positive connection between your exposure to the fragrance and your experience.
2. Please use the enclosed POSTAGE PAID Mailing Label to send your correspondence and questionnaire back to us.

We have informed our Marketing, Research and Development, and Product Safety departments of your reaction to ETERNITY.

We very much regret that you experienced this problem and thank you for bringing it to our attention. We appreciate your time and effort.

Sincerely,



May 30, 1990

Calvin Klein  
Perfumes  
725 Fifth Avenue  
New York, NY 10022

Dear Sir or Madam:

For some time I have thought of writing this letter, but I thought perhaps the problem may solve itself. I write to you now to ask that you please stop making Eternity fragrances.

Last year I noticed that every time I was near any one with a certain fragrance on, I had an asthma and allergy problem. This fragrance turned out to be "Eternity." In November I went to work for a law firm in San Francisco and a secretary on one of the floors wore this perfume. I had to ask her not to wear it because every day when I went to work I had an asthma problem. The fragrance literally enveloped the entire floor. Fortunately, she was very cooperative and stopped wearing the cologne. In December I had a party at my house and a guest came wearing this perfume. I had a violent reaction to it and had to leave my own party.

In January I started law school. A female law student who was in all of my classes had on this cologne. Once again, I had to ask the person not to wear it, or at the very least not to put as much on. She was somewhat perturbed at the request. She continued to wear it, but did reduce the amount she put on. Every night when I arrived in class I had an asthma problem and coughed throughout the class period. I noticed that later she quit using it most of the time and my coughing stopped.

My experience is not unique. I have spoken to others who have asthma and allergies and they have said Eternity also adversely affects them. The worst attribute of Eternity is that it overwhelms every other cologne or perfume within any reasonable distance, and it hangs in the air for hours. In fact, as I said before, it overpowers the entire floor of a law firm; and these floors are rather large.

Once a friend who was staying at my house sprayed the cologne in the house not realizing I would have a reaction to it. I left the windows open most of the day and left

the house. When I came home that evening, the odor was still there.

This weekend I was at the Jazz Festival in Sacramento, and many times I came in contact with someone wearing this cologne. Even walking behind someone in open air affects me to the extent that I have to use my asthma inhaler. On occasion, I have had to move from one car on the commuter train to another to avoid this cologne. I have had to get off of buses and catch another, or walk the rest of the way to the office to avoid being subjected to this cologne.

Obviously, your cologne/perfume is quite popular, and I realize this request may be somewhat out of the ordinary. In fact, I realize that Eternity probably is a great source of revenue for you. And yet it adversely affects my health every time I come in contact with it regardless of how brief that contact. I cannot ask everyone with whom I come in contact not to wear your cologne. In fact, many people with whom I come in contact I may never see again; therefore, it is pointless to ask a stranger not to wear it when the damage has already been done. My reaction to this cologne is more than mere inconvenience or dislike for the fragrance. When I get an asthma attack, I have to use inhalers in order to get my air passages open. Then I cough violently which sometimes causes me to vomit. As you can probably imagine, such an experience makes me physically very weak, often to the point that I have to go to bed and sleep for several hours.

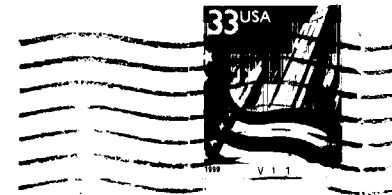
I don't know what is in your cologne that is not in others, but I do know that yours is the only cologne for women which affects me this way. Only two colognes for men have this affect, and I don't know the names. I would appreciate it if your research department would see if can determine what is in this formula that triggers asthma and allergies problems. If it cannot, I would appreciate it if you would take it off the market.

Thank you for your consideration.

Very truly yours,

Betty J. Kreeger  
1137 Shelter Creek Lane  
San Bruno, California 94066

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